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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
097554,386	07/19/00	FABRY	H-3198-PCT/U

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HM12/0605

EXAMINER
GAZI, S

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 06/05/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/554,386

Applicant(s)
Bernd Febry

Examiner
Sabiha N. Qazi

Art Unit
1616



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Mar 19, 2001
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-30 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 8
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

Final Office Action on Merits

Status of the application

Claims 11-30 are pending.

Claims 11-30 are rejected.

No claim is allowed.

Applicant's response filed in paper no. 8, dated 3/19/01 is hereby acknowledged. All the rejections are maintained for the same reasons as set forth in our previous office action. Applicant's response has been fully considered but are not found persuasive.

Applicant's argue that Mittinen reference does not teach any conjugation (first para on page 4 of the response). Examiner respectfully disagree because polyenes and monoenes are conjugated. All of them are unsaturated. At the time of invention instant invention would have obvious to one skilled in the art.

Applicant's further argue that Examiner has failed to establish a prima facie case of obviousness based upon cited references (first para of response on page 3). The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

All the basis for establishing a background for determining obviousness under 35 U.S.C. 103(a) was presented by the Examiner.

Claim Rejections - 35 USC § 103

Claims 11-30 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Miettinen et al. (EPA 594,612) in view of Alexander et al. (The New England Journal of Medicine, Vol. 318, No. 9, pages 549-547) for the same reasons set forth in our previous office action.

Instant claims are drawn to composition, preparation and method of use comprising a at least one phytosterol ester of a conjugated fatty acid having from about 6 to about 24 carbon atoms, for lowering serum cholesterol.

Miettinen et al. teaches fatty acid composition of β -sitosterol ester mixtures containing large amount of monoenes and polyenes, whereby the efficacy in lowering the cholesterol levels in serum are enhanced. See the entire document especially lines 40-45, and lines 56-58 on page 4. See also examples 1-3.

Instant claims differ from the reference in claiming at least one phytosterol ester of a conjugate acid for reducing the serum cholesterol whereas Miettinen et al. teaches that a mixture of β -sitosterol ester with polyenes or monoenes for lowering the cholesterol level.

Alexander et al. alleviates the deficiency of Miettinen et al. because it teaches the n-3 fatty acids for lowering the low-density lipoprotein (LDL) cholesterol. See last para of col. 2 on page 549. The

reference also teach dietary fish and fish oil supplements on plasma lipid levels and reduction of triglyceride levels. See Fig. 2 for the elected species eicosapentaenoic acid.

The two references are combined because they are from the same field.

One skilled in the art would find ample motivation from the prior art supra to combine the teachings of Alexander et al. and Miettinen et al. by using sterol ester and omega-3 fatty acid of known properties where the results obtained thereby are no more than the additive effects of the ingredients. In this case sterol ester and omega-3 fatty acid or ester are well known dietary supplements for lowering the cholesterol and triglyceride levels.

It would have been obvious to one skilled in the art to be motivated to prepare an stanol ester with unsaturated fatty acid to reduce the serum cholesterol because prior teaches that unsaturated fatty acid especially omega-3 fatty acid posses excellent property of reducing the serum cholesterol. Instant composition and methods would have been obvious to one skilled in the art at the time of invention.

It is a prima facie case of obviousness for one skilled in this art to use in combination two or more compositions that have been used separately for the same purpose in order to form a third composition useful for the same purpose.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill might reasonably infer from the teachings. *In re opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA 1976). A reference is not limited to working examples. *In re Fracalossi* 215 USPQ 569 (CCPA 1982).

Accordingly, the burden of proof is upon applicants to show that instantly claimed subject matter is different and unobvious over those taught by prior art. See *In re Brown*, 173 USPQ 685, 688; *In re Best*, 195 USPQ 430 and *In re Marosi*, 218 USPQ 289, 293.

In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

2. Claims 11-30 are rejected under 35 U.S.C. 103 as being unpatentable over Burdick et al. (EP 1,004,594). Burdick et al. teaches the composition of phytosterol and/or phytostanol esters with polysaturated fatty acids having 18-22 carbon atoms, which embraces applicant's claimed invention. See the entire document especially abstract and lines 3-10 on page 3 [0013]. These compositions are taught to be useful for reducing serum cholesterol and triglyceride. See sections [0015] to [0022] on page 3; table 1-5 on pages 4-5.

Instant claims differ from the reference by claiming carbon nos of conjugated acid from 6-24 where as prior art teaches from 18-22 carbon atoms. As can be seen that prior art teachings are obvious as carbon no. overlaps with the prior art teachings.

It would have been obvious to one having ordinary skill in the art at the time of the invention to select any taught by the reference, including those instantly claimed, because the skilled chemist would have the reasonable expectation that any of the species of the genus would have similar properties and, thus, the same use as taught for the genus as a whole, i.e., as useful for lowering serum cholesterol.

One having ordinary skill in the art would have been motivated to select the claimed compounds from the genus in the reference since such compounds would have been suggested by the reference as a whole. It has been held that a prior art disclosed genus of useful compounds is sufficient to render prima

facie obvious a species falling within the genus. In re Susi, 440 F.2d 442, 445, 169 USPQ 423, 425 (CCPA 1971), followed by the Federal Circuit in Merck & Co. V. Biocraft Laboratories, 874 F.2d 804, 10 USPQ 2d 1843, 1846 (Fed. Cir. 1989).

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill might reasonably infer from the teachings. *In re opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA 1976). A reference is not limited to working examples. *In re Fracalossi* 215 USPQ 569 (CCPA 1982).

Accordingly, the burden of proof is upon applicants to show that instantly claimed subject matter is different and unobvious over those taught by prior art. See *In re Brown*, 173 USPQ 685, 688; *In re Best*, 195 USPQ 430 and *In re Marosi*, 218 USPQ 289, 293.

In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

1. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory

action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Telephone Inquiry Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha N. Qazi, whose telephone number is (703) 305-3910. The examiner can normally be reached on Monday through Friday from 8 a.m. to 6 p.m. The fax phone number for this Group is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.



Sabiha N. Qazi, Ph.D.

Primary Examiner

Art Unit 1616

6/2/01